

REMARKS/ARGUMENTS

Claims 1, 3 and 5-15 remain in the application. Claims 1 and 5-13 have been amended. Claims 2, 4, 16, 24 and 25 have been cancelled. Claims 17-23 have been withdrawn.

Applicants acknowledge the Examiner's withdrawal from consideration of claims 17-23 as non-elected claims. Applicants submit that they expressly reserve any right to file continuing application(s) directed to any non-elected subject matter or request a reunion of the non-elected claims with the elected claims upon allowance of this application.

Applicants respectfully submit that the amendments have overcome the objections and rejections for reasons set forth below:

Claim Objections

In the Office Action dated April 29, 2005, claim 9 was objected to as depending from claim 9. Claim 9 has been amended to depend from claim 8.

Claim 25 was objected to as depending from claim 25, however, claim 25 has been cancelled and this objection is now moot.

Claims 12-15 were then objected as being of improper dependent form for failing to further limit the subject matter of the claims from which they depend. Claim 12 has been amended to depend from claim 5. Claim 5 has also been amended so that those claims depending therefrom have proper antecedent basis. Therefore, these amendments render the objections to claims 12-15 moot.

Provisional Obviousness-Type Double Patenting

Claims 1, 3, 5-9 and 12 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15, 43, 49 and 51 of copending application No. 10/079416.

Applicants submit that a terminal disclaimer will be filed upon allowance of the claims 1, 3, 5-9 and 12 and when claims 15, 43, 49 and 51 of copending application No. 10/079416 are found to be allowable.

Claim rejections under 35 U.S.C. §112, second paragraph

Claims 1, 3 and 6-15 were rejected under 35 U.S.C. 112, Second Paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as their invention.

Claim 1 has been amended to clarify that a composition has been claimed. Claims 3 and 6 depend from this composition. Claims 7 and 8 have been amended to depend from the method in claim 5. Claims 9-12, as amended, also depend from claim 8.

To add further clarity, claims 1, 3 and 6-15 are of the same type that the Examiner grouped as Invention I in the Election/Restriction dated February 10, 2004; wherein, the Examiner stated that claims 1-15 of Invention I were “drawn to CYP3A inhibitors alone or in combination with a drug, and methods of use.”

Therefore, with the description of Invention I in hand as well as the amendments set forth, the 35 U.S.C. §112, second paragraph rejection has been traversed.

Claim rejections under 35 U.S.C. §102(b)

Claims 1, 5 and 6 have been rejected under 35 U.S.C. §102(b) in view of Yamahara *et al.*, Journal of Ethnopharmacology (abstract). Yamahara *et al.* teach the anticholinergic action of *Swertia japonica*. Further, Yamahara *et al.* teach that when the methanol extract of *Swertia japonica* is purified and fractionated and when the component swertiamarin is present in quantities greater than thirty percent, then *Swertia japonica* was found to have anticholinergic activity.

For a claim to be anticipated under 35 U.S.C. §102(b), the reference must teach every element of the claim. (See MPEP 2131). The Yamahara *et al.* reference relied upon by the Examiner does not teach every element of the claim.

In regard to claim 1, Yamahara *et al.* does not teach or even mention the free base or pharmaceutically acceptable salt of swertiamarin as an inhibitor of CYP3A. Still further, Yamahara *et al.* does not teach that as a CYP3A inhibitor, swertiamarin, would specifically inhibit the enzymatic activity of CYP3A. Yamahara *et al.* also does not teach the free base or pharmaceutically acceptable salt of swertiamarin because the reference only teaches swertiamarin in a methanol fractionated extract.

In regard to claim 5, Yamahara *et al.* does not teach a method for inhibiting enzymatic activity in a patient or its optional use in combination with a drug that undergoes a first-pass effect. This is because Yamahara *et al.* is only directed to the anticholinergic activity of *Swertia japonica* and the fractionated components when they are present in quantities greater than thirty percent.

In regard to claim 6, Yamahara *et al.* specifically does not teach the CYP3A inhibitor element of the pharmaceutical composition claim that includes at least one pharmaceutically acceptable excipient.

Therefore, since the reference does not teach every element of claims 1, 5 and 6, the claims, as amended, traverse the rejections because the requirements for a 35 U.S.C. §102(b) rejection were not met.

Claim rejections under 35 U.S.C. §112 First Paragraph

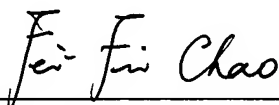
Claims 16, 24, and 25 were rejected under 35 U.S.C. §112 First Paragraph. However, claims 16, 24 and 25 have been cancelled. As a result, this rejection is moot.

Conclusion

In view of the foregoing, the objections and rejections have been overcome and the claims are in condition for allowance, early notice of which is requested. Should the application not be passed for issuance, the examiner is requested to contact the applicant's attorney to resolve the problem.

Respectfully submitted,

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Fei-Fei Chao, Ph.D. (Reg. No. 43,538)
Bingham McCutchen LLP
Three Embarcadero Center, Suite 1800
San Francisco, California 94111-4067
Tel.: (202) 778-3179
Fax: (202)-778-6155